REMARKS

Formal Matters

Claims 1-3, 5-11, 13, 25, 27-30, 32, 33 and 37-55 are pending.

Claims 1-3, 5-11, 13, 25, 27-30, 32, 33 and 37-45 were examined and are rejected.

Claims 1, 9, 25, 28, 30, 32, 33 40-43 and 45 are amended and claims 46-55 are new.
The amendments to the claims were made solely in the interest of expediting prosecution, and
are not to be construed as an acquiescence to any objection or rejection of any claim. Support
for the amendments to the claims and the new claims is found in the claims as originally
filed, and throughout the specification, in particular at the following exemplary locations:
page 13, line 33-page 14, line 8 and claim 4 as originally filed. In particular support for array
of addressable biopolymer regions may be found on page 8, lines 26-33, Fig. 2 (element 16 in
particular), and page 10, lines 28-30; support for *updated* biological function data may be
found on page 4, lines 26-27 ("*updated* sets of feature characteristic data"); page 4, lines 20-
23 ("*updated* sets"); page 5, lines 19-21 ("an *updated* set of feature characteristic data is"),
page 5, lines 2-4 and element 504 of Fig. 6. Support for the new claims may be found in the
claims as originally filed, and at the positions set forth above. Accordingly, no new matter is
added.

The Applicant respectfully requests reconsideration of the application in view of the
remarks made herein.

Interview Summary

The Applicant wishes to express his gratitude to Examiner Allen for the
telephone interview conducted on July 8, 2004, with Applicant's representatives
James Keddie and Bret Field. The outstanding rejections were discussed, as
well as arguments to overcome those rejections.

1)   Rejection of claims under 35 U.S.C. § 112, second paragraph

Claims 1-3, 5-11, 13, 25, 27-29, 32, 33 and 37-45 are rejected under 35 U.S.C. § 112,
second paragraph, as being indefinite.

The Office states that claim 6 is confusing because claim 6 is dependent on claim 1
but does not appear to limit the subject matter of claim 1.

The Applicant's understanding is that claims which are assertedly in improper

dependent form for failing to further limit the subject matter of a previous claim should be *objected to* under 37 CFR § 1.75(c)[1], not rejected under 35 U.S.C. § 112, second paragraph.

In response, however, the Applicant submits that claim 1 recites "retrieving" biological function information but does not recite "associating" the retrieved information with information obtained from reading the array, as required by claim 6. In other words, according to claim 1, the retrieved information may or may not be associated with the data obtained from reading an array. Accordingly, the Applicant respectfully submits that claim 6 is properly dependent on claim 1 because it further limits claim 1.

In view of the foregoing discussion, the Applicant respectfully submits that this rejection may be withdrawn.

The Office states that claim 9 is confusing because a period is found in the middle of the claim. This period has been removed by amendment, and, accordingly, this rejection may be withdrawn.

The Office asserts that claims 32-33 fail to further limit the processor recited in claim 30.

Again, it is the Applicant's understanding that claims which are assertedly in improper dependent form for failing to further limit the subject matter of a previous claim should be *objected to* under 37 CFR § 1.75(c)[1], not rejected under 35 U.S.C. § 112, second paragraph.

However, without wishing to acquiesce to the correctness of this rejection, claims 30, 32 and 33 have each been amended to recite a processor *adapted to* perform a particular function. Such processors include those suitably programmed to perform a particular function, as set forth in page 9, lines 23-27 and page 13, line 33 to page 14, line 8 of the specification.

Accordingly, the Applicant respectfully submits that claims 32 and 33 do limit the processor of claim 30, and, accordingly, this rejection may be withdrawn.

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[1] MPEP: 608.01(n) "Claims which are in improper dependent form for failing to further limit the subject matter of a previous claim should be *objected to* under 37 CFR 1.75(c) by using Form Paragraph 7.36. 608.01(n)" (emphasis added)

The Office re-asserts its position that the metes and bounds of claims 30 and 40 are not clear because they recite the term "indication of a suspected feature error".

The Applicant respectfully submits that in view of the specification one of skill in the array arts would readily understand what is meant by the "indication of a suspected feature error" because feature errors are not new and are, in fact, well known in the microarray arts. While the particular feature errors explicitly listed in the specification (e.g., errors relating feature presence, placement, dimensions or biopolymer concentration within a feature; see page 5, lines 4-6 and page 19, lines 25-27 of the instant specification) may be non-limiting, the Applicant respectfully submits that such examples provide sufficient guidance to allow one of skill in the art to understand the meaning of the term in question.

The subject matter claimed provides a new method for allowing data obtained from a particular feature to be associated with an indication that that feature may be an error feature (e.g., a feature that has an incorrect or unknown identity, for example). As would be recognized by one of skill in the art, any type of information may be communicated to indicate a suspected error feature, including any word, numeral, code or any other type of signal, as long as the information is sufficient to distinguish an error feature from other features.

In view of the foregoing discussion, the Applicant submits that the meaning of the term "indication of a suspected feature error" would be clear to one of skill in the art. Accordingly, this rejection may be withdrawn.

The Office asserts that claims 40-43 and 44 are confusing for referring to a method, when the claims upon which they depend are directed to an apparatus.

This inadvertent error has been corrected by amendment, and, accordingly, this rejection may be withdrawn.

The Applicant believes that claim 30 and claims dependent thereon (claims 32, 33 and 40-43) are now in form for allowance. In view of the foregoing discussion, allowance of claims 30, 32, 33 and 40-43 is respectfully requested.

2) Art-based rejections

The currently pending claims are generally directed to methods and compositions that require retrieving *updated* biological function information for biopolymers on a biopolymeric

array using a process of at least two steps. The at least two-step process generally involves: i) using an array identifier to obtain identifiers for the biopolymers present in the array features (e.g., "communicating the identifier signal to a processor which retrieves data on the identity of the biopolymers based on the read identifier"); and ii) using those identifiers for the biopolymers to obtain updated biological function information from a memory (e.g., "communicating the identity data on the biopolymers to a processor which retrieves the biological function data for one or more of the biopolymers from a memory based on the retrieved identity data"). This at least two-step process is recited in new independent claims 49 and 56 (see element (d) of claim 46, for example), and is also present in the "wherein" clause [2] added by amendment in the prior response. This wherein clause is present in independent claims 1, 9, 25 and 28.

The cited prior art methods for information retrieval can be described as "one-step" methods: an array identifier is read, and that identifier directly links the array to information for the array.

The claimed at least two-step process is not a trivial change to the prior-art one-step method because the at least two step process allows for, i.e., enables, updated biological function information to be held in a single, central database that may be at a remote location and accessed by a number of users having different arrays. The cited prior art methods simply do not provide for this feature.

In other words, using prior art methods each array or batch of arrays would have a separate database containing information on the array. However, in order to update the information for those arrays, several different databases would have to be updated (because each array or batch thereof is associated with a single database). The claimed at least two-step method recited in the claims avoids the problem of having to update several different databases when a new piece of information about the biological function of a biopolymer is discovered.

As discussed in more detail below, this at least two-step method is not disclosed, either explicitly or inherently, in any of the cited references.

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[2] "wherein the retrieval of the biological function data includes: communicating the identifier signal to a processor which retrieves data on the identity of the biopolymers based on the read identifier; and communicating the identity data on the biopolymers to a processor which retrieves the biological function data for one or more of the biopolymers from a memory based on the retrieved identity data"

Rejection of claims under 35 U.S.C. § 102 – Muraca

Claims 1-3, 5-11, 13, 25, 27-29, 37-39 and 44-45 are rejected under 35 U.S.C. § 102(e) as anticipated by Muraca (Published US Patent Application 2002168639). The Applicant respectfully traverses this rejection.

Without wishing to acquiesce to the correctness of this rejection, the rejected claims have been amended to recite an array of *addressable biopolymer regions*.

What is meant by the term "an array of addressable biopolymer regions", as recited in the claims, is explained on page 8, lines 26 to 33 of the specification. The specification teaches that an array is "an arrangement of addressable regions bearing a particular chemical moiety or moieties….associated with that region. An array is "addressable" in that it has multiple regions of different moieties…such that a region at a particular predetermined location….on the array will detect a particular target or class of targets".

Muraca's arrays are arrays of tissue samples. Since tissue samples represent a mixture of a vast number of different components, each feature of Muraca's array bears a vast number of different components. Keeping in mind the definitions set forth in the specification and repeated in the previous paragraph, the Applicants respectfully submit that Muraca's array features bear a vast number of different components and do not bear any particular chemical moiety or moieties. Further, Muraca's array does not contain *addressable* biopolymer regions because *Muraca's regions cannot detect a particular target or class of targets*. Accordingly, Muraca's tissue array falls outside of the scope of definition for what is meant by an array of addressable biopolymer regions. As such, Muraca's disclosure should have no bearing on the patentability of the instant claims.

In other words, an array of tissues samples is not an array of addressable biopolymer regions because a tissue sample represents a mixture of a vast number of different components, not a biopolymer as required by the claims. Muraca teaches an array of tissue samples is an array of addressable regions each comprising a mixture vast number of different components, not an array of addressable biopolymer regions, as required by the claims. Muraca's regions are not addressable regions of biopolymers.

At no point in Muraca's disclosure does Muraca disclose or fairly suggest that Muraca's arrays contain addressable biopolymer regions. As such, this element of the claimed invention is not taught by Muraca, and, accordingly, this rejection may be withdrawn.

In addition, because Muraca's arrays are tissue arrays, Muraca fails to disclose

retrieval of biological function data relating to a biopolymer, for example, information on a gene from which the biopolymer originated.

Finally, Muraca does not describe retrieval of *updated* biological function information, as required by the claims.

Accordingly, Muraca fails to disclose a) the array recited in the rejected claims, b) retrieval of biological function data relating to a *biopolymer*, as required by the claims, c) any type of *updated* biological function information and d) the claim—recited at least two-step method by which information may be retrieved from a database.

The Applicant respectfully submits that Muraca therefore falls well short of being an anticipatory reference, and, as such, this rejection may be withdrawn.

Rejection of claims under 35 U.S.C. § 102 – Doung

Claims 1-3, 5-11, 13, 25, 27-29, 37-39 and 44-45 are rejected under 35 U.S.C. § 102(e) as anticipated by Doung (Published US Patent Application 20020177135). The Applicant respectfully traverses this rejection.

Without wishing to acquiesce to the correctness of this rejection, the rejected claims have been amended to recite a particular method of retrieving *updated* biological information.

Firstly, the Applicant notes that the wherein clause [3] added to the claims by the previous amendment recites a particular method by which biological information is retrieved. In this Office Action, the Office stated that "this limitation is met by Doung as one of ordinary skill in the art would recognize recovery of the biological function data from the appropriate relation database would *require* such communication to a processor." (emphasis added).

Because the claim-recited method is not explicitly set forth in Doung's disclosure, this rejection is based on a theory of inherency.

The MPEP at § 2112 provides very clear guidance for establishing such rejections: "The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic."[4] (emphasis in the

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[3] "wherein the retrieval of the biological function data includes: communicating the identifier signal to a processor which retrieves data on the identity of the biopolymers based on the read identifier; and communicating the identity data on the biopolymers to a processor which retrieves the biological function data for one or more of the biopolymers from a memory based on the retrieved identity data"

[4] MPEP at § 2112, citing *In re Rijckaert,* 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993)

original). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing *may* result from a given set of circumstances is also not sufficient.[5]

The Applicant respectfully submits that the particular at least two-step retrieval method recited in the claims is not disclosed or fairly suggested by Doung, explicitly *or* inherently, since Doung does not explicitly disclose the particular claim-recited retrieval method and because many methods other than that recited in the claims may be used to retrieve the type of information from a database. For example, Doung's information may be obtained directly from a single database using a one-step method, not using the method recited in the claims.

In fact, since Doung's "information", according to paragraphs 0330-0358, is information about the cartridge (i.e., the array) used and not information about individual features on the array [6], Doung would likely retrieve that information using the most straightforward method available, i.e., by directly obtaining the information directly from a single database.

The Applicant respectfully submits that Doung cannot inherently anticipate the subject matter of the rejected claims. Doung did not necessarily use the claim recited method to retrieve information from a memory and, in fact, likely would not have used the claim recited at least two-step method because Doung's information is different to that of the rejected claims. Accordingly, while the Office may argue that there is a *possibility* that Doung's information *may* have been retrieved in the same way as that of the instant claims, the fact that such a possibility exists is insufficient grounds, according to the MPEP and current law, to reject the instant claims.

Finally, even if the Office could somehow construe Doung as disclosing the claimed

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[5] MPEP at § 2112 "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)

[6] See, e.g., Doung, paragraph 0330: :...this display may be used in conjunction with a barcode reader described below, to show the operator which cartridge was inserted (e.g. the HIV panel, the HCV panel, the infectious disease panel, the breast cancer SNP panel, etc.), or other data about the cartridge..."

array and the claimed method of retrieving information, the Applicant respectfully submits that Doung cannot be construed as disclosing retrieving *updated* biological information (either inherently or explicitly), as required by the rejected claims. In particular, because Doung's "information" is information about the cartridge (i.e., the array) used and not information about individual features on the array, Doung would have no desire to update that information because the identity of the array would not change after the array is made.

In view of the foregoing discussion, the Applicant respectfully submits that Doung fails to teach a feature of each of the pending claims. The Applicant respectfully requests withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 102 – Schembri

Claims 1-3, 5-11, 25, 27, 29, 37-39 and 44-45 are rejected under 35 U.S.C. § 102(b) as anticipated by Schembri (GB 2,319,838). The Applicant respectfully traverses this rejection.

Without wishing to acquiesce to the correctness of this rejection, the rejected claims have been amended to recite a particular method of retrieving *updated* biological function information.

Firstly, the Applicant notes that the wherein clause added to the claims by the previous amendment recites a particular method by which biological information is retrieved (see footnote 3 above). In this Office Action, the Office stated that "this limitation is met by Shembri as one of ordinary skill in the art would recognize recovery of the biological function data from the appropriate relation database would *require* such communication to a processor." (emphasis added).

Because the claim-recited method is not explicitly set forth in Schembri's disclosure, this rejection is based on a theory of inherency.

The MPEP at § 2112 provides very clear guidance for establishing such rejections: "The fact that a certain result or characteristic <u>may</u> occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." (emphasis in the original; see footnote 4 above). Accordingly, in order for such rejection to be correctly established, according to the MPEP, a claim limitation that is not explicitly taught must be inherent, i.e., necessarily present, in the cited prior art. The mere possibility that the limitation is taught in the art is not sufficient to merit such a rejection, and the mere fact that a certain thing *may*

result from a given set of circumstances is also not sufficient (see footnote 5, above).

The Applicant respectfully submits that the particular at least two-step retrieval method recited in the claims is not disclosed or fairly suggested by Shembri, explicitly *or* inherently, since Shembri does not explicitly disclose the particular retrieval method and because many methods other than that recited in the claims may be used to retrieve information from a database. For example, Shembri's information may be obtained by directly communicating with a single database, not using the method recited in the claims.

In other words, Shembri states on page 11 that "The tagged file is a file of information wherein the identity and position of each chemical moiety in the array pertaining to the file is stored" and "the information identifying in the array to a particular tagged file [e.g., a barcode] might be included on an array or its housing with the actual file stored in a data analysis device or in a computer in communication with the device", and, as such, does not explicitly disclose the particular claim recited at least two-step method. In fact, Shembri explicitly discloses a specific method in which an array barcode is read to allow direct linkage between the array and a file containing information on the identity and position of the chemical moieties on the array. This is not the method being claimed since the claimed method requires at least two steps, as set forth in footnote 3, above.

The Applicant respectfully submits that Shembri cannot inherently anticipate the subject matter of the rejected claims. Shembri did not necessarily use the claim recited method to retrieve information from a memory and, in fact, Shembri's disclosure explicitly describes a method in which a file containing information is directly linked to an array. Accordingly, while the Office may argue that there is a *possibility* that Shembri's information *may* have been retrieved in the same way as that of the instant claims, the fact that such a possibility exists is insufficient grounds, according to the MPEP and current law, to reject the instant claims.

Finally, even if the Office could construe Shembri as disclosing the claimed method of retrieving information, the Applicant respectfully submits that Shembri does not explicitly disclose retrieving *updatated* biological function information, as required by the rejected claims.

In view of the foregoing discussion, the Applicant respectfully submits that Shembri fails to teach a feature of each of the pending claims. The Applicant respectfully requests withdrawal of this rejection.

Rejection of claims under 35 U.S.C. § 102 – Ellson

Claims 25, 28 and 45 are rejected under 35 U.S.C. § 102(e) as anticipated by Ellson et al (20020086319). The Applicant respectfully traverses this rejection.

As noted above, the rejected claims recite a particular method by which biological information is retrieved (see footnote 3 above). Further and without acquiescing to the correctness of this rejection, the claims have been amended to recite retrieving *updated* biological information.

Ellson's disclosure relates to a technology in which machine readable information about the features of an array is physically attached to an array. Each array is attached to the machine readable information and the information attached to the array provides information about that array. According to paragraph 79, Ellson's technology is akin to "smart card" technology, in which the machine readable information is read to provide information.

Ellson does not disclose the particular information retrieval method recited in the instant claims. In fact, Ellson does not disclose any details of any particular information retrieval method.

As such, Ellson fails to teach an element of the rejected claims.

The Applicant further notes that Ellson's "smart cards" would bypass any need for the claim recited method of retrieving information from a memory because Ellson's information could be retrieved directly from the smart card. Accordingly, even if the Office could attempt to argue that there is a *possibility* that Ellson's information *may* have been retrieved in the same way as that of the instant claims, the fact that such a possibility exists is insufficient grounds, according to the MPEP and current law, to reject the instant claims.

Finally, even if the Office could somehow construe Ellson as disclosing the claim recited method of retrieving information, the Applicant respectfully submits that Ellson does not disclose *updated* biological function information (either inherently or explicitly), as required by the rejected claims. Ellson's information most likely does not contain updated biological information because it is affixed to the array.
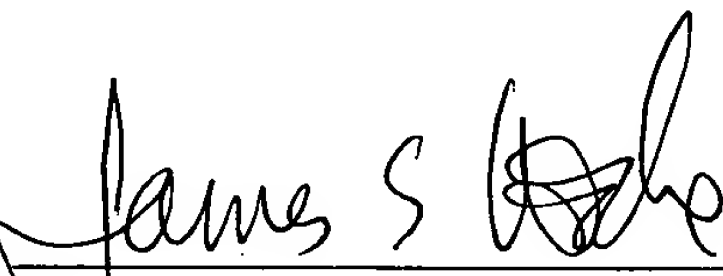
In view of the foregoing discussion, the Applicant respectfully submits that Ellson fails to teach a feature of each of the pending claims. The Applicant respectfully requests withdrawal of this rejection.
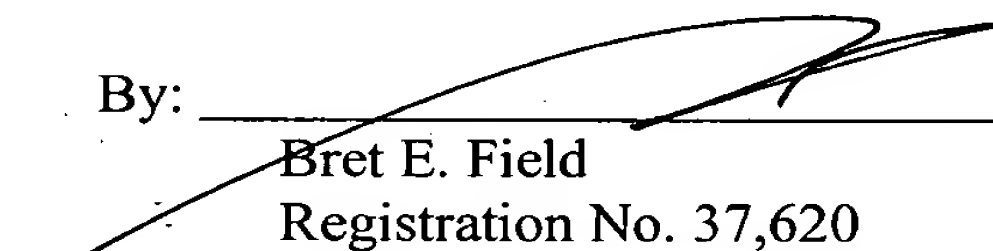
CONCLUSION

The Applicant respectfully submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone Gordon Stewart at (650) 485 2386. The Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-1078.

Respectfully submitted,

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